

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INDUSTRIENS PENSIONS Forsikring)	
A/S, Individually and On Behalf of All)	
Others Similarly Situated)	Case No. 2:20-cv-02155-SRC-CLW
)	
Plaintiff,)	
v.)	
)	OPINION
BECTON, DICKINSON AND)	
COMPANY, VINCENT A. FORLENZA,)	
THOMAS E. POLEN, and)	
CHRISTOPHER R. REIDY,)	
)	
Defendants.)	
)	

CHESLER, District Judge

This matter comes before the Court on the motion to dismiss brought by Defendant Becton, Dickinson and Company (“BD” or the “Company”) and individuals Vincent Forlenza, Thomas Polen and Christopher Reidy (the “Individual Defendants” and, collectively with BD, “Defendants”)¹ regarding Plaintiff Industriens Pensionsforsikring’s (“Plaintiff”) Third Amended Complaint (the “TAC”) against them. Plaintiff opposes the motion.

In a Memorandum and Order dated September 15, 2021 (the “September 2021 Decision”) the Court granted Defendants’ motion to dismiss Plaintiff’s Second Amended Complaint for failure to state a claim. (ECF Nos. 87–88.) Since then, Plaintiff has repleaded with additional details, but the gravamen of the complaint has not changed. Plaintiff brings this putative class

¹ Plaintiff alleges that certain of the statements at issue were made by John Gallagher, BD’s then-Senior Vice President, -Treasurer, and -CFO. (TAC ¶¶ 211, 309.)

action pursuant to the Private Securities Litigation Reform Act of 1995 (“PSLRA”), 15 U.S.C. § 78u-4(a)(3)(B), on behalf of all persons or entities who purchased or otherwise acquired the common stock of BD between November 5, 2019, and February 5, 2020, inclusive (the “Class Period”). The TAC asserts three causes of action: (1) a claim for violation of Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a, *et seq.* (the “Exchange Act”) against Defendants, (2) a control person claim pursuant to Section 20(a) of the Exchange Act against the Individual Defendants, and (3) an insider trading claim pursuant to Sections 10(b) and 20A of the Exchange Act against Defendants Forlenza and Polen.

The Court has considered the Parties’ written submissions, proceeds to rule without argument pursuant to Federal Rule of Civil Procedure 78(b), and will grant in part and deny in part Defendants’ motion to dismiss the TAC. Plaintiff has failed to establish a strong inference of scienter with respect to Defendants Forlenza and Reidy, and all claims against them will be dismissed. Furthermore, Plaintiff has failed to plausibly allege a material misstatement or omission with respect to statements made in connection with BD’s issuance of the February 4, 2020 “voluntary recall” notifications, and thus Plaintiff’s claims relying on these statements will be dismissed. Defendants’ motion is otherwise denied and Plaintiff’s claims against Defendants BD and Polen may proceed.

I. BACKGROUND

BD is a New Jersey-based medical technology company engaged primarily in manufacturing and selling medical devices, instrument systems, and reagents. (TAC ¶ 31.) BD’s business is comprised of three business segments: BD Medical, BD Life Sciences, and BD Interventional. (TAC ¶ 33.) BD’s Medication Management Solutions (“MMS”) unit, which is

housed within BD Medical, focuses primarily on infusion systems and dispensing technologies. (TAC ¶ 35.)²

In 2015, BD acquired CareFusion Corp. (“CareFusion”), a San Diego-based medical technology company giving BD the right to manufacture, market, and distribute the Alaris infusion pump system and associated technologies. (TAC ¶¶ 60–61.) Infusion pumps are electronic, external medical devices that deliver fluids into a patient’s body in a controlled manner and commonly are used to deliver blood, nutrients, or medications such as insulin, antibiotics, chemotherapy drugs, and pain relievers. (TAC ¶ 60.) These pumps consist of both hardware and software in their operation and are often paired with related devices and software platforms in comprehensive “medication management” systems. (TAC ¶ 61.) Due to their use in administering critical fluids to high-risk patients, the infusion pumps’ consistent and accurate operation, along with sufficient training and appropriate use, is important to avoid potential injury, including death, to the patients using them. (TAC ¶ 63.)

A. Federal Regulation of Infusion Pumps

Because of its use in medical processes, infusion pumps are subject to regulation by the Food and Drug Administration (the “FDA”) pursuant to the Food, Drug, and Cosmetic Act (the “FD&C Act”), as amended by the Medical Device Amendments of 1976. (TAC ¶ 64.) The FDA classifies infusion pumps as “Class II” medical devices (TAC ¶ 65), as they possess the potential

² Forlenza served as BD’s Chief Executive Officer (“CEO”) from October 2011 until January 2020 and at all relevant times also served as the Chairman of the Board of Directors. (TAC ¶ 43.) Polen served as BD’s President since 2017 and from October 2014 to April 2017 he was the Executive Vice President and President of the BD Medical Segment. (TAC ¶ 44.) Polen also served as BD’s Chief Operating Officer until January 2020, at which time he replaced Forlenza as CEO. (TAC ¶ 44.) Reidy served as BD’s Executive Vice President, Chief Financial Officer (“CFO”), and Chief Administrative Officer since July 2013. (TAC ¶ 45.)

for dangerousness and “general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness.” 21 U.S.C. § 360c(a)(1)(B).

To regulate these devices, the FDA requires manufacturers to establish quality control mechanisms ensuring that the devices meet current good manufacturing practice standards. 21 C.F.R. § 820.30. For Class II devices, a manufacturer’s quality control systems must involve documenting and maintaining records relating to software or other design changes, including any analysis, testing, and decisions associated with software changes to its medical devices.³ The failure to comply with regulatory standards may result in the issuance of a Form 483—used by the FDA to notify manufacturers of significant objectionable conditions or violations discovered during inspections—a warning letter, fines, seizure or recall of products, or product bans. (TAC ¶ 70.) The FDA may also seek a court order enjoining individuals and corporations from continuing to violate the FD&C Act or recommend criminal prosecution by the Justice Department. (TAC ¶ 70.)

As Class II medical devices, infusion pumps must be approved for distribution and monitored with respect to device changes through the FDA’s Premarket Notification 510(k) Program. (TAC ¶ 72.) This program requires that a manufacturer of a Class II device submit to the FDA a 510(k) application when: (i) introducing a device into commercial distribution for the first time; or (ii) introducing “[a] change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process” or “[a] major change

³ See 21 C.F.R. § 820.30 (manufacturer must establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met); 21 C.F.R. § 820.70 (manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure); 21 C.F.R. § 820.181 (manufacturer must document changes and approvals in the device master record); *see also Deciding When to Submit a 510(k) for a Software Change to an Existing Device*, U.S. Food & Drug Admin., Oct. 25, 2017.

or modification in the intended use of the device.” 21 C.F.R. § 807.81(a). To obtain approval through the 510(k) process, the manufacturer must demonstrate that its device is at least as safe and effective as, or “substantially equivalent” to, an existing device that has already been approved. *Id.* The manufacturer must submit a 510(k) application at least ninety days before it intends to begin marketing the device. *See* 42 Fed. Reg. 42520, 42522 (Aug. 23, 1977) (“[T]he burden is on the manufacturer to determine whether a premarket notification should be submitted for a change or modification in a device. The Commissioner believes that the manufacturer is the person best qualified to make this determination.”).

Manufacturers are further required to report certain device-related adverse events and product problems to the FDA, including when they become aware that: (i) any of their devices may have caused or contributed to a death or serious injury; or (ii) their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. 21 C.F.R. § 803. The company may then do one of three things: (i) propose a correction; (ii) remove the product from the stream of commerce; or (iii) voluntarily recall the product. *Id.*⁴ In some circumstances, corrections related to voluntary recalls may be implemented while the device continues to be marketed and remains in use and available in the field. (TAC ¶ 84.)⁵

⁴ The FDA classifies recalls based on the degree of risk associated with the defective device. A Class I designation is the most serious and indicates that there is a reasonable chance that a defective product will cause serious health problems or death. A Class II designation indicates that a product may cause a temporary or reversible health problem, or that there is a slight chance that it will cause serious health problems or death. A Class III designation indicates the defective product is not likely to cause any health problem or injury. (TAC ¶ 85.)

⁵ Alaris has been the subject of a number of safety concerns over the years. In August 2006, Cardinal Health, Alaris’s then-manufacturer, initiated a Class I recall of certain Alaris models due to the potential for over-infusion caused by a software issue. (TAC ¶ 92.) The U.S. Department of Justice subsequently filed a complaint against Cardinal Health and Cardinal Health entered into a consent decree with the FDA on February 7, 2007 setting forth certain requirements that Cardinal Health must follow to resume the manufacture and sale of the Alaris SE pumps (the “Consent Decree”). (TAC ¶ 71.) Following these continuing defects and violations, the Consent Decree was amended in February 2009 to include all models of the Alaris infusion pumps then produced (the “Amended Consent Decree”). (TAC ¶ 74.) The Amended Consent Decree has applied to Alaris manufactures since then and continued to be in effect through the Class Period. (TAC ¶ 93.)

B. The Alaris Infusion Pump

Alaris first received 510(k) clearance over 25 years ago, in 1995. (TAC ¶ 95.) Since then, it has been manufactured and marketed by a variety of entities, including Cardinal Health, CareFusion, and BD. (TAC ¶¶ 92–93.)⁶

On October 5, 2014, BD entered into an agreement to acquire CareFusion, which at the time manufactured Alaris and other products. (TAC ¶ 86.) The acquisition closed on March 17, 2015 and CareFusion became a part of the Medication Management Solutions division within BD’s Medical segment. (TAC ¶¶ 86–87.) The CareFusion acquisition doubled the size of the Medical segment, and during the Class Period the Medical segment provided more than half of BD’s total annual revenues. (TAC ¶¶ 34, 87.)

Before and during the Class Period, BD and its representatives touted Alaris products as a “Key Brand” driving BD revenues and an important component in a suite of interoperable medical devices which BD manufactured and sold. (TAC ¶ 102–06.) Prior to the Class Period, Alaris constituted approximately 70% of the infusion pump market, and was a source of continuous revenue growth for BD Medical and BD. (TAC ¶¶ 108–109, 127.) Underscoring the general interest investors had in Alaris’s financial performance, the product line was regularly the subject of questions posed to BD management by investment analysts. (*See, e.g.*, TAC ¶¶ 108, 112, 115.)

1. Alaris Presents a Persistent Low Battery Alarm Defect.

In November 2016, BD recalled over half a million Alaris units in connection with a failure of Alaris’s low battery alarm and very low battery alarms to trigger (the “LBA defect”). (TAC

⁶ Since 2002, Alaris manufacturers collectively filed six 510(k) applications in connection with changes and modifications to the device. (TAC ¶ 95.) BD did not obtain 510(k) approval for changes it made to Alaris from the time it acquired Alaris through the end of the Class Period. (TAC ¶ 95.)

¶ 96.) A device impacted by this defect would stop an ongoing infusion without prior warning with potentially dangerous consequences. (TAC ¶ 96.) According to the TAC, notwithstanding this recall the LBA defect continued to plague Alaris and was the subject of continued scrutiny by both BD and the FDA.

- i. *BD submits and subsequently withdraws a 510(k) application concerning, among other things, updates relating to the LBA defect.*

In 2017, BD launched “Project Monterey,” an effort to prepare and submit a 510(k) submission to address certain software issues with Alaris, including the LBA defect. (TAC ¶ 156.) Project Monterey resulted in BD’s submission of a 510(k) application in November 2017 BD. (TAC ¶¶ 157, 159.)

In or around April 2018, the FDA provided “preliminary feedback” to BD about the Company’s 510(k) submission. (TAC ¶ 162.) This feedback highlighted numerous shortcomings with the submission, including that the Company’s documentation was incomplete and insufficient. (TAC ¶¶ 158, 160, 162.) The FDA informed BD that, prior to approving the submission, the FDA required additional documentation and data, including information related to substantive revisions of Alaris software that BD had already made to the device. (TAC ¶¶ 158, 160, 162.) According to one confidential witness, this feedback “presented a problem” because BD did not have the documentation and data that the FDA had requested. (TAC ¶ 161.) BD withdrew the 510(k) submission in or around June 2018 as a result of the deficiencies identified by the FDA and in order to avoid a negative formal determination. (TAC ¶¶ 158, 162.) BD did not disclose to the public the existence of Project Monterey or the related 510(k) submission. (TAC ¶ 163.)

Following BD's withdrawal of the 510(k) application, Polen sought an analysis to determine why the application was insufficient and later received reports detailing the reasons why the application had failed. (TAC ¶ 164.)

- ii. *The FDA issues a Form 483 highlighting continuing problems with respect to the LBA defect.*

From July to September 2018, the FDA conducted an inspection of the facility where Alaris is developed, tested, and manufactured. (TAC ¶ 148.) At the conclusion of the inspection, the FDA issued a Form 483 to BD which detailed various deficiencies with Alaris-related quality systems and the product generally (the "September 2018 Form 483"). (TAC ¶ 148.) Among other issues identified in the September 2018 Form 483, it described continued problems related to the LBA defect and stated that the LBA defect "had not been fixed" despite the earlier recall. (TAC ¶¶ 148, 150.)

In a written response to the Form 483 which BD submitted to the FDA in September 2018, the Company stated that it had determined that 510(k) clearance was required relating to fixes designed to correct the LBA defect. (TAC ¶¶ 149, 153.)⁷ According to one confidential witness, as an "immediate step" following BD's receipt of the September 2018 Form 483, BD gave customers a temporary "work around" for the issue: the Company told customers to "throw out" Alaris batteries after two years. (TAC ¶ 151.)

⁷ According to one confidential witness, BD acknowledged to the FDA on at least one other occasion in 2018 that remediation of the LBA defect would require a new 510(k) clearance. (TAC ¶ 154.)

2. BD Representatives Meet with the FDA Beginning in Late Summer 2019 Concerning Alaris Software Issues, Resulting in a Ship Hold Announced in November 2019.

A series of meetings between BD and the FDA concerning Alaris began in approximately August 2019. (TAC ¶¶ 127–28.) According to FE-6, a senior executive in the Quality function at BD Medical’s MMS unit from 2016 through the spring of 2020 who “interacted directly” with the FDA in and around August 2019, the FDA approached BD as a result of another pump manufacturer’s recall related to a “Keep Vein Open” (“KVO”) battery alarm. (TAC ¶ 127). In connection with this inquiry, BD collected and provided information on Alaris alarms to the FDA. (TAC ¶ 130.) After reviewing the information, the FDA conveyed to BD representatives that certain issues “needed to be fixed” and sought a “larger meeting” with BD management to discuss these issues. (TAC ¶¶ 130–31.)

Representatives of BD met again with the FDA in September or October 2019 (the “Fall 2019 Meeting”). BD’s delegation for this meeting included Keith McLain (BD’s Global Head of Quality for MMS), Bhupesh Mahendru (Head of Quality for the Infusion Division of MMS), Michelle Badal (VP of Regulatory Compliance in the Quality function at MMS), BD’s Global Head of Regulatory Affairs for MMS, and FE-6, among others. (TAC ¶¶ 124, 132.) The attendees discussed potential issues with the KVO battery alarm, “changes and fixes that had already been made to the Alaris software,” and additional software fixes necessary to address other “anomalies and issues.” (TAC ¶ 133.) The attendees also discussed the LBA defect that the FDA identified in the September 2018 Form 483. (TAC ¶ 134.) According to FE-6, FDA representatives conveyed that the various issues discussed at the meeting were “concerning” and said: “You

should have been fixing these issues. You should do a 510(k). We don't think you should be shipping this product with these issues.” (TAC ¶ 135.)⁸

According to FE-6, “as soon as” the FDA expressed its concerns at this meeting, BD put Alaris on ship hold, and the TAC elaborates that Mahendru and McLain made the decision to do so within hours of this meeting. (TAC ¶¶ 136–41).

BD announced the ship hold during an investor call on November 5, 2019. (TAC ¶¶ 123, 177.)

3. BD Briefly Lifts the Ship Hold in December 2019 But Reinstates It After Discussions with the FDA in January 2020.

After BD announced the ship hold, the Company endeavored to determine which of the Alaris issues and anomalies “needed a 510(k)” and which potentially did not. (TAC ¶ 180.) The MMS unit’s Quality and R&D functions worked through November and December 2019 to resolve certain anomalies in the Alaris software, but failed to address larger, “more significant” problems, such as the LBA defect. (TAC ¶ 180.) Concurrent with those efforts, BD prepared a 510(k) submission “package” for the identified Alaris problems, including the LBA defect. (TAC ¶ 181.) At least certain “safety fixes” were completed by mid-December 2019, though other issues remained unaddressed. (TAC ¶ 183.)

The FDA again met with BD representatives, including FE-6, to discuss Alaris “a few weeks after the ship hold began,” in “roughly” December 2019. (TAC ¶ 178.) When asked by the

⁸ Multiple confidential witnesses corroborate elements of this meeting and describe conversations that they had with certain meeting participants. For example, one witness recounted a conversation with Mahendru where Mahendru relayed that the FDA “dictated” that the ship hold be imposed (TAC ¶¶ 138–39), while another witness reported that Badal informed him that the FDA “had placed a freeze” on shipping Alaris. (TAC ¶ 140.) Other confidential witnesses also report more generally that the FDA was aware of various software defects prior to the ship hold. (TAC ¶¶ 142–43.)

FDA whether BD was shipping Alaris, McLain, BD's lead representative in the meeting, responded that it was not, which was true at the time. (TAC ¶ 178.)⁹

Immediately following this meeting, BD implemented certain changes to the Alaris software. (TAC ¶ 184.)¹⁰ While these changes were designed to fix certain Alaris anomalies, they did not correct the LBA defect or other significant issues which BD purportedly knew would require 510(k) clearance. (TAC ¶ 184.) After implementing these changes, and shortly before December 25, 2019, BD lifted the ship hold and resumed Alaris shipments and sales. (TAC ¶ 185.) BD did not inform the FDA of the Company's intention to lift the ship hold before it resumed the Alaris shipments. (TAC ¶ 185.)

Approximately three weeks after BD resumed shipping Alaris, McLain and other BD representatives (again including FE-6) met with FDA representatives via a conference call. (TAC ¶¶ 189–90.) During the call, BD informed the FDA that the Company had resumed shipping Alaris. (TAC ¶ 190.) In response to this information, the FDA “expressed disappointment, questioned BD's representatives and heard their rationale.” (TAC ¶ 190.) During the call the FDA reaffirmed its prior position and stated that BD needed to obtain 510(k) clearance for the required Alaris changes, including the changes in question that BD had just made to the software. (TAC ¶ 190.)

BD immediately after the conference call reimplemented the Alaris ship hold. (TAC ¶ 190.) According to FE-6, the resumption of the ship hold was “reported up the chain of command through senior management within an hour or so.” (TAC ¶ 191.)

⁹ The TAC also describes a separate “pre-submission” communication that the FDA had with BD in the winter of 2019–2020 in which the FDA asked BD to confirm that Alaris was on a ship hold. (TAC ¶ 179.) BD confirmed that the ship hold remained in place, which was true at the time of the communication. (TAC ¶ 179.)

¹⁰ According to one confidential witness, these changes were implemented “over a weekend” after the meeting with the FDA. (TAC ¶ 186.)

C. The Class Period and the Allegedly Misleading Statements

The TAC avers that beginning on November 5, 2019 and throughout February 6, 2020, Defendants made numerous statements which were allegedly misleading due to their failure to acknowledge severe issues with respect to Alaris' performance and ongoing FDA scrutiny of the device. Defendants, Plaintiff maintains, communicated information about BD that was not consistent with this awareness.

1. November 5, 2019 - Announcement of Fiscal Year 2019 Earnings and Fiscal Year 2020 Guidance

On November 5, 2019, BD issued a press release announcing its earnings for fiscal year 2019 and issuing guidance for 2020 (the "FY20 Guidance"). (TAC ¶ 196.) According to the TAC, the Individual Defendants made a number of misleading statements of material fact in the press release and during an investor call which BD conducted later that day. These include:

- Statements by Reidy that "fourth quarter performance in the Medical segment was driven by ongoing momentum and share gains in [MMS] and continued strength in Pharmaceutical Systems." (TAC ¶ 197.)
- The announcement by Forlenza and Reidy regarding the FY20 Guidance, including revenue growth of 5% to 5.5% and earnings per share between \$12.50 and \$12.65. Reidy added that the Company was forecasting strong revenue growth of 4% to 5% in BD Medical. (TAC ¶ 198.)
- Statements made by Reidy concerning the Alaris ship hold. Reidy told investors that BD's overall revenue growth would be approximately 1% lower in the first half of FY20 than the full fiscal year's revenue growth of 5% to 5.5%, and that the first half's lower guidance resulted from expected "first quarter revenue growth of 1% to 2%." Reidy attributed this lower guidance to the ship hold, which was in place to allow BD to implement "some improvements to our Alaris pump software, including upgrades to alarm prioritization and optimization."

Reidy further stated: "We are in discussions with the FDA about the timing of implementation of these upgrades and the possibility of bundling them with a new software version release. This is expected to move the timing of some sales from Q1 to the balance of the fiscal year." (TAC ¶¶ 199–201, 301.)

- Statements by Polen that Alaris was the “clear leader and product choice” in the infusion pump market, further stating that “it’s part of our process and our strategy in the business to continually iterate and make enhancements to the platform. . . . And this upgrade right here is a continued reflection on those investments.” Polen also highlighted the “record levels of continued share gain” in the infusion business, and represented to investors that “we see no slowdown in that momentum.” (TAC ¶¶ 202, 304.)

According to Plaintiff, these statements: (i) “obfuscated the FDA’s central role” in the ship hold; (ii) misrepresented these changes as “upgrades” when they were in fact “a number of significant patient safety issues;” (iii) misrepresented the extent and severity of the Alaris issues underlying the ship hold; (iv) misrepresented the fact that, with respect to at least the LBA defect, BD had acknowledged to the FDA that a 510(k) was required; and (v) misrepresented the scope of work and amount of time that BD would require to remediate the identified problems. (TAC ¶¶ 305–07.) Plaintiff further asserts that these statements were materially false and misleading because they lacked a reasonable basis in fact and misrepresented BD’s financial condition and growth prospects. (TAC ¶ 308.)

2. November 21, 2019 - Jefferies London Healthcare Conference

The TAC identifies a number of alleged misrepresentations made by John Gallagher, BD’s then-Senior Vice President, -Treasurer, and -CFO, on November 21, 2019 while he was speaking on behalf of BD at the Jefferies London Healthcare Conference. At the conference, Gallagher reiterated the November 5, 2019 guidance regarding the timing of BD’s expected revenue in fiscal year 2020. (TAC ¶¶ 211–12.) When asked to describe the factors driving the FY20 Guidance, he stated:

One of the larger ones to call out as well is Alaris pumps. We’re upgrading some software. This is in our MMS business, our infusion pumps. We’re upgrading some software in the pumps, and that will delay some

installations and shipment into the subsequent quarters, and we anticipate getting all of that back inside of the fiscal year.

(TAC ¶¶ 212, 312.) Gallagher also asserted that BD “expect[ed Alaris’] momentum to continue when you look at the full year of fiscal ‘20.” (TAC ¶¶ 213, 315.)

3. November 27, 2019 - Form 10-K

On November 27, 2019, the Company filed its FY19 Form 10-K for the period ending September 30, 2019, which was approved, signed, and certified by Forlenza and Reidy. (TAC ¶ 319.) According to the TAC, the Form 10-K made materially false or misleading statements that “characterized as contingent or speculative risks that had already come into being or that were reasonably projected to occur.” (TAC ¶ 328.) Namely, according to the TAC, the statements in the Form 10-K were at odds with the Company’s failure to comply with applicable regulations,¹¹ failure to comply with the Amended Consent Decree,¹² and failure to obtain necessary approvals with respect to Alaris.¹³

¹¹ See TAC ¶ 320 (“Our failure to comply with the applicable good manufacturing practices, adverse event reporting, and other requirements of these agencies could delay or prevent the production, marketing or sale of our products and result in fines, delays or suspensions of regulatory clearances, warning letters or consent decrees, closure of manufacturing sites, import bans, seizures or recalls of products and damage to our reputation.”).

¹² See TAC ¶¶ 322 (We may be obligated to pay more costs in the future because, among other things, the FDA may determine that we are not fully compliant with the amended consent decree and therefore impose penalties under the amended consent decree As of September 30, 2019, we do not believe that a loss is probable in connection with the amended consent decree”), 324 (“The consent decree authorizes the FDA, in the event of any violations in the future, to order us to cease manufacturing and distributing products, recall products or take other actions, and we may be required to pay significant monetary damages if we fail to comply with any provision of the consent decree.”).

¹³ See TAC ¶ 326 (“Delays in obtaining necessary approvals or clearances from the FDA or other regulatory agencies or changes in the regulatory process may also delay product launches and increase development costs . . . [and] [m]anufacturing or design defects, component failures, unapproved or improper use of our products, or inadequate disclosure of risks or other information relating to the use of our products can lead to injury or other serious adverse events. These events could lead to recalls or safety alerts relating to our products . . . and could result, in certain cases, in the removal of a product from the market. . . . In some circumstances, such adverse events could also cause delays in regulatory approval of new products or the imposition of post-market approval requirements.”); see also TAC ¶ 94 (“BD actively maintains FDA/ISO Quality Systems that establish standards for its product design, manufacturing, and distribution processes. Prior to marketing or selling most of its products, BD must secure approval from the FDA and counterpart non-U.S. regulatory agencies. . . . These regulatory controls, as well as any changes in FDA policies, can affect the time and cost associated with the development, introduction, and continued availability

4. December 4, 2019 - Evercore HealthCONx Conference

On December 4, 2019, Defendant Reidy attended and spoke at the Evercore HealthCONx Conference and repeated some of the earlier statements at issue. When asked by an analyst whether “anything changed at all in the competitive side for” BD, Reidy responded: “No. Actually, the [infusion] pump side, we’ve been taking 200 points of share last year, and we see that continuing, and we have some visibility to that. So we don’t see that being the case.” (TAC ¶¶ 214, 331.) Reidy also referred to the “great advantages” that Alaris provided by virtue of connectivity across BD’s product lines. (TAC ¶ 331.) Furthermore, Reidy made several statements concerning revenue deferrals in the Alaris product line, referring to these deferrals as a result of “a timing issue.” (TAC ¶¶ 215, 333–34.)

5. January 14, 2020 - JPMorgan Healthcare Conference

On January 14, 2020, Reidy and Polen attended and spoke at the JPMorgan Healthcare Conference and presented an investor slide deck entitled “Introducing the Next Phase of Value Creation for BD,” which was later published on BD’s website. (TAC ¶ 337.) Polen reaffirmed BD’s FY20 Guidance and once more reassured investors that BD was “very much on track for the full year” FY20 Guidance. (TAC ¶ 338.) Polen declared that BD had “[f]ully resumed shipping [Alaris products] in the first quarter.” (TAC ¶ 342.) When asked by an analyst whether the shipping deferral “played out as expected,” Polen responded: “Exactly as expected.” (TAC ¶ 343.)

6. January 28, 2020 - Annual Shareholders Meeting

On January 28, 2020, the Company held its Annual Shareholders Meeting and provided investors with a presentation entitled “Annual Meeting of Shareholders,” which was published on

of new products. . . . These agencies possess the authority to take various administrative and legal actions against BD, such as product recalls, product seizures and other civil and criminal sanctions.”).

BD's website. (TAC ¶ 345.) During the shareholders' meeting, Defendant Forlenza again represented that BD was "on track" to meet its FY20 Guidance. (TAC ¶ 346.)

7. February 4, 2020 – BD Issues a Voluntary Recall Notification

On February 4, 2020, BD issued a notification (the "February 4 Recall Notices") announcing that it was issuing a "voluntary recall" to address "specific software issues with the BD Alaris™ System Infusion Pumps." (TAC ¶¶ 231, 350–51.) In the February 4 Recall Notices, BD advised customers that it would undertake "comprehensive education and support" concerning the software issues and patch "an upcoming software release." (TAC ¶ 234.) The February 4 Recall Notices did not indicate that Alaris devices would be unavailable for sale for any period of time, nor did it disclose that the FDA had informed BD that it needed 510(k) clearance for the previously implemented software changes. (TAC ¶¶ 234, 238.)

D. BD Discloses the Need for 510(k) Approval

On February 6, 2020, BD issued a Form 8-K with an attached earnings press release disclosing that the FDA required BD to obtain 510(k) clearance for historical software changes and that BD was required to halt all Alaris sales. (TAC ¶¶ 239–42.) It also lowered its Company-wide earnings guidance for FY20 and lowered the forecast for Alaris revenues to zero for the balance of FY20. (TAC ¶ 241.) Shortly after the issuance of the earnings release, BD held a pre-market conference call regarding BD's first quarter FY20 earnings during which Polen discussed the new guidance and a "key meeting" BD had with the FDA earlier that week:

So as I mentioned, based on the quality system in our Infusion business, we've made software upgrades over time to the Alaris system. And over that period of time, we're talking – not this year, we're talking a number of years, our quality process determined that those upgrades that we've been making in that business did not require a 510(k) clearance. And so most recently, on the most recent changes and updates that we made, we followed that same process. And our team determined based on that process that

those recent updates in November also did not require a new 510(k) clearance. And so we released that software improvement in December, and we resumed shipping, as we had shared with you last month.

Since what we've learned, and as I mentioned, we had a key meeting with the FDA as recently as this Monday, through our ongoing dialogue with the FDA, we learned that the FDA disagreed with that determination about the need for a new 510(k) clearance for the updated software. And that applies not just to the upgraded software that we're talking about in November, but that decision process that had occurred over time. And so as I said, we're collaborating with the FDA on their request to combine all the Alaris software enhancements and remediation upgrades with the additional changes made to the Alaris system over time, right, over years, into a more comprehensive regulatory filing, which is going to be submitted this summer. And so while you're right, we are ready to – we have the information ready for the recent software upgrades, we are – the work that has to take place between now and the submission date is more in reference to the historical changes that have been made over multiple years going back, and the – some additional testing that we need to do on those historic changes to reflect the testing requirements today. So that's the work that has to be done.

(TAC ¶ 250.) Upon the disclosure of the news BD's stock price declined \$33.74—nearly 12%—with unusually heavy trading volume. (TAC ¶ 253.)

In a subsequent investor call, on May 7, 2020, Polen told investors that the 510(k) application for Alaris was “the critical priority for the company.” (TAC ¶ 259.) He asserted that “the executive team” was “directly engaged” on the Alaris project “on a daily and weekly basis.” (TAC ¶ 259.) BD ultimately did not submit a 510(k) application for Alaris until April 26, 2021, well after the Class Period. (TAC ¶¶ 250, 258–61.)

E. Individual Defendants Forlenza's and Polen's Trading Histories

During the Class Period, Defendant Forlenza sold 198,137 shares of BD common stock for total proceeds of \$54,668,240.95. (TAC ¶¶ 359–60.) Nearly all Forlenza's sales were made pursuant to a 10b5-1 trading plan that he entered on December 16, 2019—during the Class Period.

(TAC ¶ 274.) Defendant Polen sold 13,907 shares of BD common stock on or about December 16, 2019 for total proceeds of \$3,749,744.41. (TAC ¶¶ 359–60.)

II. DISCUSSION

On a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), the Court must apply the standard of review articulated by the Supreme Court in *Bell Atlantic Corp. v. Twombly* and *Ashcroft v. Iqbal*. Under this standard, a complaint will survive a motion under Rule 12(b)(6) only if it states “sufficient factual allegations, accepted as true, to ‘state a claim for relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007)). A complaint states a plausible claim if it “pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). While the complaint need not demonstrate that a defendant is probably liable for the wrongdoing, allegations that give rise to the mere possibility of unlawful conduct will not do. *Id.*; *Twombly*, 550 U.S. at 557.¹⁴

A. Securities Fraud Claim Under § 10(b) of the Exchange Act

Section 10(b) of the Exchange Act provides that a person or entity may not “use or employ, in connection with the purchase or sale of any security, . . . any manipulative or deceptive device or contrivance in contravention of [the U.S. Securities and Exchange Commission (the “SEC”)] rules and regulations.” 15 U.S.C. § 78j(b). Rule 10b-5(b), in turn, makes it unlawful to “make any untrue statement of material fact or to omit to state a material fact in order to make the

¹⁴ Defendants ask that the Court rely on the law of the case doctrine to “refrain from re-deciding the issues” it resolved in the September 2021 Decision. (Dfts.’ Br. at 16.) In the case of a motion to dismiss, the law of the case doctrine does not apply where, as here, “new allegations have been made which change the nature of the record and place it in an altogether different state than it was in at the time the Court decided the issue at hand.” *Farmer v. Lanigan*, 2016 WL 4107693, at *3 (D.N.J. Aug. 1, 2016).

statements made, in light of the circumstances under which they were made, not misleading.” 17 C.F.R. § 240.10b-5(b)(2). To state a claim under Rule 10b-5, a plaintiff must allege facts establishing each of the following elements: (1) a material misrepresentation or omission; (2) scienter; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014).

Claims brought pursuant to Section 10(b) of Exchange Act and the statute’s implementing regulation Rule 10b-5 are subject to certain heightened pleading requirements under the PSLRA. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 320–21 (2007) (noting that prior to the enactment of the PSLRA, the pleading standard of Rule 9(b) governed the sufficiency of a complaint for securities fraud). The PSLRA mandates that, to survive a motion to dismiss, a complaint must (1) “specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed” and (2) “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. §§ 78u-4(b)(1) & (2); 15 U.S.C. § 78u-4(b)(3)(2) (“In any private action arising under this chapter, the court shall, on the motion of any defendant, dismiss the complaint if the requirements of [15 U.S.C. §§ 78u-4(b)(1) & (2)] are not met.”). The PLSRA’s particularity requirement echoes the heightened standard set forth in Federal Rule of Civil Procedure 9(b), applicable to general claims of fraud. *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir. 2009).

Defendants challenge the sufficiency of the Rule 10b-5 claim on the same grounds as those asserted in their opposition to Plaintiff’s Second Amended Complaint. They argue that the TAC

fails to set forth particularized facts indicating why the alleged actionable statements and omissions were misleading, fails to plead scienter with the requisite particularity, and fails to plead loss causation.

1. Plaintiff sufficiently alleges material misstatements or omissions.

To allege a material misstatement or omission under Rule 10b-5, Plaintiff must plead with particularity that Defendants “made a materially false or misleading statement or omitted to state a material fact necessary to make a statement not misleading.” *Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000) (quotations omitted). It is well-established that “[a]bsent a duty to disclose, silence is not fraudulent or misleading under Rule 10b-5 When you speak, however, and it is material, you are bound to speak truthfully.” *U.S. v. Schiff*, 602 F.3d 152, 162 (3d Cir. 2010) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 239 n.17 (1988)); see also *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1432 (3d Cir. 1997) (“Except for specific periodic reporting requirements[,]. . . there is no general duty on the part of a company to provide the public with all material information.”). A duty to disclose under Rule 10b-5 may arise in three circumstances: “when there is insider trading, a statute requiring disclosure, or an inaccurate, incomplete or misleading prior disclosure.” *Oran*, 226 F.3d at 285–86. An omission may constitute a violation of Rule 10b-5 only where there is “a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information made available.” *MatriXX Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (quoting *Basic*, 485 U.S. at 231–32); see also *Oran*, 226 F.3d at 282 (holding same).

- i. *Allegedly misleading statements regarding the precipitating cause and ongoing risk of the ship hold.*

While “disclosure is not a rite of confession, and companies do not have a duty to disclose uncharged, unadjudicated wrongdoing,” *City of Pontiac Policemen’s and Firemen’s Retirement System v. UBS AG*, 752 F.3d 173, 183–84 (2d Cir. 2014), Defendants may not describe “a favorable picture” of material issue “without including the details that would have presented a complete and less favorable one,” *SEB Inv. Mgmt. AB v. Endo Int’l, plc*, 351 F. Supp. 3d 874, 897 (E.D. Pa. 2018). The TAC, bolstered over its predecessor by allegations derived by new and knowledgeable confidential witnesses, adequately pleads that Defendants were obligated to disclose the material, adverse reason why the ship hold had been implemented.

During the Fall 2019 Meeting, FDA representatives expressed their position that the various issues discussed at the meeting were “concerning” and said: “You should have been fixing these issues. You should do a 510(k). We don’t think you should be shipping this product with these issues.” (TAC ¶ 135.) The TAC also contains allegations from multiple confidential witnesses demonstrating that critical employees working on Alaris and its defects—including at least one individual, Mahendru, with the decision-making authority to instate the ship hold (TAC ¶ 136)—understood that the FDA in this meeting *de facto* demanded the imposition of a ship hold until the BD could resolve the defects. (See TAC ¶¶ 138–39 (alleging that Mahendru relayed to FE-9 that the FDA “dictated” the imposition of a ship hold); 140 (alleging that Badal informed FE-10 that the FDA “had placed a freeze” on shipping Alaris).)

Defendants challenge the allegations attributed to FE-9 and FE-10 as “rank hearsay unaccompanied by any indicia of reliability.” (Dfts.’ Br. at 44.) This argument fails to appreciate the level of corroborating information, the TAC contains more than enough detail to meet its burden at this stage of the proceedings. When considering allegations made by confidential

witnesses, courts should assess the “‘detail provided by the confidential sources, the sources’ basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia.’” *Avaya*, 564 F.3d at 261 (quoting *Cal. Pub. Emps.’ Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 147 (3d Cir. 2004)). The TAC alleges enough detail about FE-9 and FE-10 to “support the probability that a person in the position occupied by the [FEs] would possess the information alleged.” *Chubb*, 394 F.3d at 148. Plaintiff alleges that FE-9 and FE-10 worked under and reported directly to the meeting participants to whom they respectively attribute accounts of the meeting. (TAC ¶¶ 56–57.) FE-9 and FE-10’s respective job title and functions further support the plausibility that they would have the information alleged. (TAC ¶¶ 56–57.) Accepting these allegations as true, as the Court must, Plaintiff has satisfactorily alleged how the FEs “had access to such information.” *Avaya*, 564 F.3d at 263; *see also Pelletier v. Endo Int’l plc*, 439 F. Supp. 3d 450, 468 n.8 (E.D. Pa. 2020) (“the [FE] allegations are specific, mutually consistent, and plausibly within the scope of knowledge each [FE] would have acquired during his or her employment”).

Defendants further argue that FE-9’s and FE-10’s recounting of their respective conversations are inconsistent with the first-hand account of the meeting which FE-6 provided, and that if the FDA had said these things, “presumably they would appear in the allegations attributed to FE-6.” (Dfts.’ Br. at 44–45.) The Court does not read Plaintiff’s allegations so narrowly so to construe these various allegations as inconsistent. In any event, even if the allegations could be construed as inconsistent, the TAC pleads that decisionmakers understood the FDA’s position as adverse and inflexible. The conclusion that the FDA communicated its determination that Alaris must be placed on a ship hold—and that BD understood as much—is corroborated further by the urgency with which the Company responded: Immediately following

its meeting with FDA representatives, BD renewed its efforts to create the 510(k) application for needed Alaris fixes. (TAC ¶¶ 166, 175, 181–82.)

Reidy’s, Polen’s, and Gallagher’s subsequent statements which spoke directly to the ship hold—such as those issued on November 5, 2019, November 21, 2019, December 14, 2019—misrepresented the material, adverse reason underlying and nature of the ship hold.¹⁵ *Williams v. Globus Med., Inc.*, 869 F.3d 235, 241 (3d Cir. 2017) (company may not omit material fact from public disclosure that renders it misleading); *Merck*, 2011 WL 3444199, at *9 (“the disclosure required by the securities laws is measured” by material’s ability “to accurately inform rather than mislead”). The fact that the FDA had not issued a formal warning letter that required BD to cease shipping Alaris products does not mean that the Company was free to issue misleading statements that failed to recognize the serious, immediate, and known risks posed by a near-certain enforcement action. *See, e.g., Gov’t of Guam Ret. Fund v. Invacare Corp.*, 2014 WL 4064256, at *7 (N.D. Ohio Aug. 18, 2014) (“Defendants appreciated the gravity of the FDA’s concerns, knew the risks facing the Company, yet downplayed and mischaracterized them in disclosures to the investing public.”); *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 350 (E.D. Pa. 2014) (“When the FDA tells a company about problems with a product, and the company nonetheless continues to make confident predictions about a product, courts have inferred scienter and falsity.”); *In re Merck & Co., Inc. Sec., Derivative & “ERISA” Litig.*, 2011 WL 3444199, at *10 (D.N.J. Aug. 8, 2011) (“positive statements” about drug misleading “for failure to completely

¹⁵ The TAC does not allege that Defendant Forlenza spoke about the ship hold or the reasons underlying the same at any time during the Class Period.

and accurately represent [negative] information known” at same time). Future action against the Company could hardly at this time be considered mere speculation.¹⁶

Nor does the fact that Reidy disclosed on November 7, 2019 that it was “in discussions with the FDA” regarding software upgrades concerning “alarm prioritization and optimization” and a “new software release” immunize Defendants from liability. (TAC ¶¶ 199, 301.) Defendants did not disclose that the FDA findings regarding numerous Alaris defects had directly precipitated the ship hold: the FDA provided express and unambiguous feedback at the meeting that the Company should not be shipping the product and that the Company should file a 510(k) application after BD failed to fix numerous “concerning” problems with the Alaris software. *In re Bristol-Myers Squibb Sec. Litig.*, 2005 WL 2007004, at *23 (D.N.J. Aug. 17, 2005) (“a defendant may choose silence or speech based on the then-known factual basis, but cannot choose half-truths”); *Hall v. Johnson & Johnson*, 2019 WL 7207491, at *16 (D.N.J. Dec. 27, 2019) (“[b]y placing the nature of the Company’s” conduct “in play,” defendants acquired duty to disclose adverse facts); *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 590 (D.N.J. 2001) (actionable misrepresentation where company failed to attribute result to true source).

Of course, Defendants’ statements must be evaluated in the context of all available information. *Omnicare, Inc. v. Laborers Dist. Council Const. Ind. Pension Fund*, 575 U.S. 175,

¹⁶ In contrast, the authorities on which Defendants rely involve facts demonstrating that regulatory action was far more speculative than that at issue here. See *McClain v. Iradimed Corp.*, 111 F. Supp. 3d 1293, 1300, 1303-04 (S.D. Fla. 2015) (complaint dismissed where allegations failed to show that the FDA indicated that Iradimed would need to submit a new 510(k) application until the FDA sent defendants a warning letter asserting as much, which the company promptly disclosed); *In re PolarityTE, Inc., Sec. Litig.*, 2020 WL 6873798, at *11-13 (D. Utah Nov. 22, 2020) (dismissing securities fraud claim where, at time the company disclaimed that no “governmental proceedings are pending against us or, to our knowledge, contemplated against us,” where the company notified governmental authorities of “suspected significant illegal trading in [PolarityTE’s] securities and the only action taken against the company by the SEC was an initial inquiry and request for documents”); *Hoey v. Inmed Inc.*, 2018 WL 902266, at *14 (D.N.J. Feb. 15, 2018) (dismissing action where defendant failed to disclose communications that amounted to “mere questioning” by the regulator that had the “primary purpose” of facilitating continued discussion between the company and the regulator).

190 (2015)). But even when considering the available information—a mix that includes, as the TAC acknowledges, problems with the Alaris suite of products¹⁷—Defendants cannot escape the conclusion that their statements were misleading. While the investing public was well-aware that BD had not received any new 510(k) clearances for Alaris since the Company acquired it in March 2015, as far as the investing public was aware any risk that the FDA would require a new 510(k) application to address these issues was highly speculative throughout the Class Period. While investors are charged with the knowledge that BD would have a “[c]ontinuous dialogue” with the FDA regarding regulated products, *In re Amarin Corp. PLC Sec. Litig.*, 689 F. App’x 124, 132 (3d Cir. 2017) (quoting *Tongue v. Sanofi*, 816 F.3d 199, 211 (2d Cir. 2016)), when BD spoke about its discussions with the FDA, it was obligated to speak truthfully and disclose material information that “significantly altered the ‘total mix’ of information made available” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011)).¹⁸

Similarly, statements made by the Defendants Reidy and Polen on January 14, 2020¹⁹ about the purported successful resumption of Alaris sales in December 2019 are misleading because they did not disclose the critical fact that the FDA had not known of BD’s resumption of

¹⁷ See TAC ¶¶ 92 (describing the consent decree and amended consent decree); 96 (“Alaris was periodically the subject of device recalls.”)

¹⁸ Defendants’ argument that the determination of whether to file a 510(k) submission is consigned to the manufacturer in the first instance is unavailing: Inherent in this regulatory scheme is the FDA’s authority to express its disagreement and override the manufacturer’s determination. While Defendants push the narrative that “BD learned of FDA’s determination on February 3, 2020 and disclosed it three days later” (Dfts.’ Br. at 48), Plaintiff has sufficiently alleged that this impending determination was conveyed to BD during the Fall 2019 Meeting.

¹⁹ At or around the time of this announcement, BD again had a conference call with FDA representatives at which BD informed the FDA that it had resumed shipping Alaris. (TAC ¶ 190.) As recounted by FE-6, who participated in the meeting, the FDA rejected BD’s argument for resuming Alaris shipments and reaffirmed its prior position that BD needed to obtain a 510(k) for various software changes. (TAC ¶ 190.) While it is unclear whether this meeting occurred before or after the January 14, 2020 statements, the TAC adequately alleges that it occurred prior to the Company’s January 28, 2020 statements. (TAC ¶¶ 184, 190 (alleging that this conference call occurred “approximately three weeks” after BD lifted the ship hold, which occurred prior to December 25, 2019).)

Alaris sales when it had earlier stated that Alaris should not be shipped. *SEB Inv. Mgmt.*, 351 F. Supp. 3d at 897, 900 (defendant may not describe “a favorable picture” of material issue “without including the details that would have presented a complete and less favorable one”); *In re Mannkind Sec. Actions*, 835 F. Supp. 2d 797 (C.D. Cal. 2011) (refusing to dismiss claims where defendants claimed that the FDA had “blessed,” “approved,” “accepted,” and “agreed to” the company’s methodological approach in its clinical trials, when it later became evident that the FDA had not done so).²⁰

ii. *Allegedly misleading statements regarding the contingency of Alaris-related risks.*

“Cautionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired.” *S.E.C. v. Tecumseh Holdings*, 765 F.Supp.2d 340, 352 (S.D.N.Y. 2011) (emphasis in original) (quoting *Rombach v. Chang*, 355 F.3d 164, 173 (2d Cir. 2004)); see e.g., *In re MobileMedia Sec. Litig.*, 28 F. Supp. 2d 901, 930 (D.N.J. 1998) (finding allegation that defendants’ warning of possible difficulties with acquired company’s subscriber base actionable when they were already experiencing integration difficulties). “[T]o caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit,” in violation of Rule 10b-5. *In re Westinghouse Sec. Litig.*, 90 F.3d 696, 710 (3d Cir. 1996). According to Plaintiff, disclosures found in BD’s 10-K were misleading insofar as certain of these risks had already materialized. (Pltf.’s Br. at 28–29.) The risks at issue here—“delay[s] or prevent[ion of] the production, marketing or sale of [BD’s] products,” “fines, delays or suspensions of regulatory

²⁰ Defendants suggest that they are immune from liability because the TAC does not “explain which precise ‘issues’ the FDA thought needed fixing, let alone suggest a determination by the FDA that *all* prior modifications to Alaris needed 510(k) clearance prior to continued shipment.” (Mot. at 22.) Plaintiff need not establish that “all” prior modifications needed 510(k) clearance to establish falsity. *In re Majesco Sec. Litig.*, 2006 WL 2846281, at *6 (D.N.J. Sept. 29, 2006) (particularity “does not demand an exhaustive cataloging of facts”); *RealTech Sys. Corp.*, 173 F. Supp. 2d 129, 137 (S.D.N.Y. 2001) (fraud pleadings do not require specificity that can be achieved only through discovery).

clearances” (TAC ¶ 320), the “impos[ition of] penalties under the amended consent decree” (TAC ¶ 322) or “[d]elays in obtaining necessary approvals or clearances from the FDA” (TAC ¶ 326)—had materialized at the time BD made these disclosures.²¹

As the Court explained in the September 2021 Decision, “[these] risk[s] focus[] on the possibility that an agency determination could impact the sale of Alaris products.” ECF No. 87 at 27 (citing *Williams*, 869 F.3d at 242) (emphasis omitted). “Th[ese] risk[s are] not manifest until the Company is aware of such a determination” *Id.* Here, the Company was put on notice of the FDA’s intention that Alaris should be put on hold and a new 510(k) application submitted. The Company was further aware that obtaining the required clearances would take many months, during which Alaris could not be marketed or sold. (TAC ¶¶ 138, 167.) At the time BD issued the 10-K, the risk that Alaris faced imminent delays was manifest, whether or not that risk yet impacted the Company’s bottom-line. *Odeh v. Immunomedics, Inc.*, 2020 WL 4381924, at *6 n.6 (D.N.J. July 31, 2020) (actionable risk disclosure treated issue that had occurred as “hypothetical issue”); *In re Innocoll Holdings Pub. Ltd. Co. Sec. Litig.*, 2020 WL 1479128, at *17 (E.D. Pa. Mar. 25, 2020) (finding false and misleading risk disclosure); *Meyer v. Jinkosolar Holdings Co., Ltd.*, 761 F.3d 245, 251 (2d Cir. 2014) (“[a] generic warning of a risk will not suffice when undisclosed facts on the ground would substantially affect a reasonable investor’s calculations of probability”).

iii. *Allegedly misleading statements regarding Alaris sales and BD’s FY20 Guidance.*

Defendants further argue that the risk disclosures are protected by the PSLRA’s safe harbor. The PSLRA contains a “safe harbor” provision that immunizes defendants from liability

²¹ The one exception to this is BD’s imposition of an Alaris ship hold, the existence of which BD disclosed on November 5, 2019, prior to the issuance of the Form 10-K. (TAC ¶¶ 123, 177.) This disclosure was materially misleading for the reasons previously discussed. *Supra* 20–25.

under Section 10(b) for “forward-looking statements,” such as statements of future economic performance. 15 U.S.C. §78u–5(i)(1)(B). This immunity applies if the forward-looking statement is identified as such and “is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement” or the plaintiff fails to prove the forward-looking statement “was made with actual knowledge by [the speaker] that the statement was false or misleading” *OFI Asset Mgmt. v. Cooper Tire & Rubber*, 834 F.3d 481, 490 (3d Cir. 2016) (quoting 15 U.S.C. §78u–5(i)(1)(B)).

a) Defendants’ statements of present facts were materially misleading.

As the Court acknowledged in the September 2021 Decision, certain of the disclosures regarding the FY20 Guidance included both forward-looking statements and statements of present fact. “[A] mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present.” *Avaya*, 564 F.3d at 255; *In re Dr. Reddy’s Lab’y Ltd. Sec. Litig.*, 2019 WL 1299673, at *18 (D.N.J. Mar. 20, 2019) (“The mere fact that a statement contains *some* reference to a projection of future events cannot sensibly bring the statement within the safe harbor if the allegation of falsehood relates to non-forward-looking aspects of the statement.”). These statements include various characterizations of Alaris software updates (TAC ¶¶ 301, 313, 331, 334, 341–42). These statements were misleading insofar as they omitted the critical detail underlying the upcoming software updates: The planned “improvements” to the software were the result of the FDA’s views (which BD representatives understood to be inflexible) about the LBA defect, previously implemented changes to the software since BD’s last successful 510(k) application, and other software anomalies. *Supra* at 21–**Error! Bookmark not defined.**26.

- b) Defendants’ forward-looking statements were not accompanied by meaningful cautionary language.

While cautionary language accompanied certain statements at issue (*see* ECF No. 87 at 30–31), the new allegations found within the TAC leads to the conclusion that they were not meaningful in nature. The cautionary language found within the November 27, 2019 10-K—which the Court found applicable to statements made at the January 14, 2020 conference and the January 28, 2020 shareholder meeting—is insufficient in light of the allegations in the TAC because the risks the 10-K warned of had already materialized at the time BD issued the document. *See supra* Section II.A.1.ii. For similar reasons, the disclaimers which accompanied BD’s November 5, 2019 statements— which identified such risk factors as “difficulties inherent in product development . . . ; product efficacy or safety concerns resulting in product recalls or actions being taken by the FDA or other regulators”—did not account for the obvious jeopardy that the FDA’s position conveyed during the Fall 2019 Meeting posed to Alaris sales. *In re Prudential Sec. Inc. Ltd. Partnerships Litig.*, 930 F.Supp. 68, 72 (S.D.N.Y. 1996) (the safe harbor’s principles “provides no protection to someone who warns his hiking companion to walk slowly because there might be a ditch ahead when he knows with near certainty that the Grand Canyon lies one foot away”).

- c) Forward-looking guidance was provided without a reasonable basis.

While “[t]he federal securities laws do not obligate companies to disclose their internal forecasts . . . if a company voluntarily chooses to disclose a forecast or projection, that disclosure is susceptible to attack on the ground that it was issued without a reasonable basis.” *In re Burlington Coat Factory*, 114 F.3d at 1427. A projection lacks a reasonable basis if it was made after inadequate consideration of available information. *Id.* at 1429. According to Plaintiff, Defendants’ Class Period statements about the FY20 Guidance and related statements about BD’s

revenues and Alaris sales in FY20 were unreasonable because these projections depended on strong Alaris sales in FY20, which Plaintiff contends “were highly improbable (or worse) because of the FDA action that Defendants concealed.” (Pltf.’s Br. at 40.)

The inferences that Plaintiff proposes that the Court adopt are pleaded sufficiently to conclude that the projections at issue failed to have a “reasonable basis.” In light of the FDA’s unambiguous feedback at the Fall 2019 Meeting, the FY20 Guidance and subsequent forward-looking statements—which relied on durable Alaris sales in FY20—was unmoored from the Company’s immediate reality. *See, e.g., Curran v. Freshpet, Inc.*, 2018 WL 394878, at *5 (D.N.J. Jan. 9, 2018) (financial projection actionable where defendants failed to disclose manufacturing problems); *In re AT&T Corp. Sec. Litig.*, 2002 WL 31190863, at *15 (D.N.J. Jan. 30, 2002) (growth projections actionable where at odds with “serious operational problems”); *In re Advance Auto Parts, Inc., Sec. Litig.*, 2020 WL 599543, at *3 (D. Del. Feb. 7, 2020). The extraordinary risk that FDA action posed to Alaris sales in light of the product’s software problems, and the lengthy period of time that BD would require to resolve these problems, were highly material.²²

iv. *Allegedly misleading statements in the February 4 Recall Notices*

While Plaintiff has sufficed to demonstrate numerous misleading statements regarding the Alaris software defects, it has not shown that the February 4 Recall notices are actionable. Plaintiff does not allege that the February 4 Recall Notices are materially false,²³ rather it contends that

²² While Defendants contend that the FDA’s history of inaction in the face of purported compliance violations supports the conclusion that the Company had a reasonable basis in making its projections, this argument fails to appreciate the substantial updates which Plaintiff made to its allegations over and above the Second Amended Complaint: It was not reasonable to continue to believe that the FDA would not take action when the FDA at the Fall 2019 Meeting conveyed—and representatives of the Company understood—that BD should halt marketing and shipping Alaris in light of the many software issues

²³ As the Court noted in the September 2021 Decision, “[n]owhere in the pleadings does Plaintiff allege that the devices that had been delivered and installed were or became unusable, notwithstanding the existence of the recall.” ECF No. 87 at 32–33.

they were misleading by “failing to disclose that the FDA had rejected BD’s resumption of Alaris sales and reaffirmed the need for a new 510(k) [submission].” (Pltf.’s Br. at 52.) Given that the TAC does not allege that the previously delivered and installed Alaris devices were or became unusable following the FDA’s action, the February 4 Recall Notices do not speak to future Alaris sales or regulatory approval. *Cf. Williams*, 869 F.3d at 241 (“[O]nce a company has chosen to speak on an issue—even an issue it had no independent obligation to address—it cannot omit material facts related to that issue so as to make the disclosure misleading.”). Simply pointing the Court to omitted details, as Plaintiff has done, and failing to explain how the omitted details rendered the February 4 Recall Notices misleading, misses the mark.

2. Plaintiff’s allegations concerning scienter.

Both the PSLRA and Federal Rule of Civil Procedure 9(b) impose heightened pleading requirements on plaintiffs who allege securities fraud. Rule 9(b) requires that “[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.” The PSLRA requires that a securities fraud complaint “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u–4(b)(2). A plaintiff may establish this strong inference “either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.” *In re Burlington Coat Factory*, 114 F.3d at 1418. In analyzing scienter the Court considers “not only inferences urged by the plaintiff . . . but also competing inferences rationally drawn from the facts alleged.” *Tellabs*, 551 U.S. at 314. A complaint adequately pleads scienter under the PSLRA

“only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” *Id.* at 324.²⁴

Having evaluated whether “all of the facts alleged, taken collectively,” *Tellabs*, 551 U.S. at 323, the Court finds that the Complaint sufficiently establishes a strong inference of scienter as demanded by the PLSRA only as to Polen and BD. Plaintiff has failed to meet their pleading burden with respect to statements made by Forlenza, Reidy, or Gallagher.²⁵

- i. *Plaintiff has established facts sufficient to support the strong inference of scienter as to Polen and, by extension, BD.*

The TAC is bolstered by allegations derived from a number of new confidential witnesses, certain of which allege to be knowledgeable regarding the communications in late 2019 and early 2020 between the FDA and BD representatives. These new allegations—particularly those derived from FE-6’s personal knowledge—taken as true, establish a strong inference that Polen was aware during the Class Period that the FDA required that BD halt its shipments of Alaris and receive comprehensive 510(k) approval prior to the resuming those shipments.

Considering first whether the Polen was knowledgeable of the Fall 2019 Meeting, Plaintiff has met its burden to show strong inference of scienter. In relying on FE-6 to demonstrate Polen’s

²⁴ To evaluate the scienter of a corporate defendant such as BD, courts “look to the state of mind of the individual corporate official or officials who make or issue the statement” *C. of Roseville Emps.’ Ret. Sys. v. Horizon Lines, Inc.*, 713 F. Supp. 2d 378, 402 (D. Del. 2010). A corporate defendant cannot be held liable “absent a showing that at least one individual officer who made, or participated in the making of, a false or misleading statement did so with scienter.” *Id.* at 403 (citation omitted).

²⁵ The Parties disagree over whether the statements at issue must be made with an “intent to deceive” investors in order for an actionable claim to lie. (*Compare* Dfts.’ Br. at 33 with Pltf.’s Br. at 46 n.1.) Of course, the reckless omission of facts can also give rise to the scienter required for Plaintiff to meet its pleading burden. *In re Hertz Glob. Holdings Inc.*, 905 F.3d at 114 (quoting *Avaya*, 564 F.3d at 252). Given that the TAC pleads sufficiently that Polen knew of facts which rendered his statements misleading, the Court can conclude that Plaintiff has sufficiently pleaded that Polen’s failure to disclose those facts was at least reckless. *See In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 539 (3d Cir. 1999) (“A reckless statement is a material misstatement or omission ‘involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care’ and ‘which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it.’”)

knowledge of this critical meeting, the TAC alleges that FE-6, who is alleged to have had “overall leadership responsibilities for the Quality function for . . . Alaris” and to have been “personally involved in reporting up and out about . . . meetings and outcomes,” informed MMS Business Head Banerjee, who informed Head of the BD Medical Business Alberto Mas, who informed then-President and -COO Polen about the meeting. (TAC ¶ 145.) While the TAC alleges that FE-6 “does not know the precise date Polen was informed about the FDA meetings and ship hold,” FE-6 asserts that Polen was informed before the ship hold was announced on November 5, 2019. (TAC ¶ 145.) When considered holistically these allegations suffice to meet Plaintiff’s burden of providing the “who, what, when, where and how” of the Individual Defendants’ knowledge of the relevant and undisclosed facts. *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 239 (3d Cir. 2004).

Defendants’ efforts to discredit FE-6 as an unreliable confidential witness are unavailing. FE-6 is alleged to have had “overall leadership responsibilities for the Quality function for . . . Alaris” and to have been “personally involved in reporting up and out about . . . meetings and outcomes,” and thus was in a meaningful position to report on the facts alleged in the TAC. Moreover, the TAC alleges with specificity the reporting chain which led from FE-6 to Polen.²⁶ *Compare In re Cambrex Corp. Sec. Litig.*, 2005 WL 2840336, at *11 (D.N.J. Oct. 27, 2005) (finding allegations sufficient where confidential witness had personal knowledge concerning defendants’ knowledge of accounting errors) *with Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 244 (3d Cir. 2013) (granting motion to dismiss where the confidential witnesses did not have “any way of knowing what was discussed in . . . closed-door meetings[,] . . . [and did] not provide any dates

²⁶ The inference that Polen would be informed of the meeting with the FDA is further supported by his historical awareness of and involvement in Alaris’s prior, failed 510(k) application in connection with Project Monterey. (TAC ¶¶ 163–64, 286.)

for the meetings, explain how they would know that the [fraudulently altered] labels were moved from one office to another, or claim to have attended any of the meetings or even entered any of the management offices.”); *Martin v. GNC Holdings, Inc.*, 757 F. App’x 151, 155 (3d Cir. 2018) (“[T]he confidential witnesses [failed to] provide specific facts about [defendants] learning of the potentially tainted products prior to making the actionable statement”).

Similarly, the updated allegations plausibly assert that Polen was aware of the FDA’s communications with BD following the imposition of the November 2019 ship hold, supporting the inference that Polen was kept informed of the Company’s relationship with the FDA as it concerned Alaris. FE-6 reports of a meeting with the FDA that occurred “approximately three weeks after BD unilaterally lifted the ship hold,” after which “BD immediately put the ship hold back in place.” (TAC ¶ 190.) According to FE-6, this decision was “reported up the chain of command” and news of the meeting “quickly went to everyone.” (TAC ¶ 190.) These allegations are corroborated by FE-8, an employee within BD’s Regulatory Affairs function, who is alleged to have attended a meeting in “January or February 2020” at which Polen “discussed the Alaris ship hold and 510(k) filing.” (TAC ¶ 167.) While Defendants urge the Court to consider the counter-inference that this meeting with FE-8 could have occurred after the February 3, 2020 communications with the FDA, the inference that this meeting occurred prior to February 3 is “at least as compelling” as the one Defendants propose. *Tellabs*, 551 U.S. at 324. Ultimately, Plaintiff’s new allegations amount to more than mere “blanket assertions” that Polen “‘knew’ that the representations were untrue.” *Klein v. Autek Corp.*, 147 F. App’x 270, 277 (3d Cir. 2005).²⁷

²⁷ While Plaintiff has pled that Polen (and thus BD) had the requisite state of mind with respect to Polen’s utterances, the Plaintiff does not meet its burden with respect to the written representations issued on or around the time of those utterances. In *Winer Family Trust v. Queen*, 503 F.3d 319, 335–37 (3d Cir. 2007), the Third Circuit held that “the group pleading doctrine is no longer viable in private securities actions after the enactment of the PSLRA,” effectively foreclosing the “judicial presumption that statements in group-published documents including annual reports and press releases are attributable to officers and directors who have day-to-day control or involvement in regular company operations.” Here, Plaintiff has failed to include allegations “specifically tying [Polen] to the

In addition to these allegations, Plaintiff argues that several other factors support a finding that Polen acted with scienter: (i) his public statements; (ii) the importance of Alaris to the business; and (iii) his trading history. At best, these factors, considered individually or collectively, are only marginally in favor of finding scienter “when viewing the entirety” of the complaint. *Roofers’ Pension Fund v. Papa*, 2018 WL 3601229, at *24 (D.N.J. July 27, 2018). In light of the TAC’s allegations concerning Polen’s personal knowledge of the FDA’s communications, Plaintiff has met its burden at this phase of the litigation.

Polen’s Public Statements. According to Plaintiff, Polen held himself out to investors as knowledgeable about and engaged with the Company’s discussions with the FDA. (Pltf.’s Br. at 47.) In particular, Plaintiff highlights prepared remarks given by Reidy and Polen on November 5, 2019 in which they “discussed the ship hold in detail, made characterizations about modifications to Alaris, how long the ship hold was expected to last, related communications with the FDA, and answered analyst questions.” (Pltf.’s Br. at 47 (citing TAC ¶¶ 296–304).)

The fact that the Polen held himself out as knowledgeable concerning the conversations with the FDA—one of BD’s primary regulators²⁸—tends to support the inference that he was aware of the FDA’s feedback within the meetings when considered with the allegations of Polen’s particular knowledge of the underlying facts. *See Allegheny Cnty. Emps.’ Ret. Sys. v. Energy*

drafting of the press release[s]” or other presentation materials issued in connection with the November 5, 2019 earnings call and the January 14, 2020 conference. *See, e.g., Biondolillo v. Roche Holding Ag*, 2018 WL 4562464, at *6 (D.N.J. Sept. 24, 2018) (finding scienter sufficiently pled against CEO, who issued statements following a press release, with respect to his statements, but not with respect to those misrepresentations or omissions found within the preceding press release).

²⁸ The SEC’s current and ongoing investigation into matters concerning Alaris pumps (TAC ¶¶ 264–65) is another, albeit minor, factor the Court considers in determining that Plaintiff has pleaded scienter sufficiently. *Papa*, 2018 WL 3601229, at *21 (“There mere [sic] fact of the investigation is somewhat probative of scienter.”); *Washtenaw Cnty. Emps. Ret. Sys. v. Avid Tech., Inc.*, 28 F. Supp. 3d 93, 115 (D. Mass. 2014) (government investigation “one more piece of the puzzle” in scienter analysis).

Transfer LP, 532 F. Supp. 3d 189, 228 (E.D. Pa. 2021) (inferring scienter where executive “held himself out to investors as knowledgeable” by speaking “in detail” about project); *SEB Inv. Mgmt.*, 351 F. Supp. 3d at 906 (defendants’ public comments “confirm they had intimate knowledge of the data. Indeed, that is what they wanted the public, particularly investors, to think. These officers were speaking as authoritative sources who possessed the information to support their statements”); *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, at *16-17 (D.N.J. Aug. 28, 2017) (speaking “explicitly and repeatedly” about results and company’s talks with FDA supported scienter); *Frater*, 996 F. Supp. 2d at 349 (statements “impl[ied]” that speakers knew “the FDA’s feedback”).²⁹

Alaris and the Core Operations Doctrine. While the Third Circuit has consistently rejected the argument that a defendant’s “position” within a company, even an important position, creates an inference of scienter, *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 539 (3d Cir. 1999), “misstatements and omissions made on ‘core matters of central importance’ to the company and its high-level executives give rise to an inference of scienter when taken together with additional allegations connecting the executives’ positions to their knowledge.” *In re Urban Outfitters*, 103 F. Supp. 3d at 653–54 (quoting *Rahman*, 736 F.3d at 246–47); *see also Nat’l Junior Baseball League v. Pharmanet Dev. Grp. Inc.*, 720 F. Supp. 2d 517, 556 (D.N.J. 2010) (“[A] person’s status

²⁹ Plaintiff further argues that Polen and Reidy’s statements at the February 6, 2020 investor call concerning BD’s “ongoing conversations” and “dialogue” with the FDA “imply[] their knowledge of the FDA’s interactions with BD all along.” (Pltf.’s Br. at 47 n.33 (citing TAC ¶¶ 246, 250, 252).) While post-class period statements may be relevant to a plaintiff’s claims, *see, e.g., Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 183 (S.D.N.Y. 2010), “this proposition has significance only when contradictory information is properly alleged to have been available to defendant in the first place—i.e., only when the post-class period statements actually do confirm what defendant knew or should have known.” *Sinay v. CNOOC Ltd.*, 2013 WL 1890291, at *8 (S.D.N.Y. May 6, 2013), *aff’d*, 554 F. App’x 40 (2d Cir. 2014). The post-Class Period statements at issue do not suggest in any way that the executive team became involved with or knowledge about the ongoing “dialogue” with the FDA prior to February 3, 2022, nor do they establish what the Individual Defendants knew during the Class Period. Accordingly, they do not weigh in favor of finding scienter here.

as a corporate officer, when considered alongside other allegations, can help support an inference that this person is familiar with the company's most important operations.”). “[I]t is not automatically assumed that a corporate officer is familiar with certain facts just because these facts are important to the company's business; there must be other, individualized allegations that further suggest that the officer had knowledge of the fact in question.” *In re Heartland Payment Sys., Inc. Sec. Litig.*, 2009 WL 4798148, at *7 (D.N.J. Dec. 7, 2009). A product need not have an outsized impact on a company's financial performance to constitute a “core operation”; products that present substantial reputational risk may suffice as well. *Hall v. Johnson & Johnson*, 2019 WL 7207491, at *21 (D.N.J. Dec. 27, 2019) (inferring scienter to executives speaking about a product that accounted for 0.3% of the company's sales); *Energy Transfer*, 532 F. Supp. 3d at 232-33 (applying “core operations” doctrine to small revenue project with independent reputational value core operation).

Here, BD Medical made up over half of BD's total annual revenue in 2017, 2018, and 2019 (TAC ¶ 36), and BD reported BD Medical's underlying revenue growth was “driven” by the “[MMS] unit's installation of dispensing and infusion systems.” (TAC ¶ 282.) Alaris was billed as a “Key Brand” which, as Forlenza acknowledged before the Class Period, was “fuel[ing] growth” for BD. (TAC ¶¶ 104–12, 282.) The importance of Alaris's central role in a suite of interoperable products further enforces its role as a key revenue driver for the Company. (TAC ¶¶ 102–03, 283.) And, investment analysts frequently asked BD's leadership specific, probing questions regarding Alaris's performance, underscoring the importance of the product to BD's value. (TAC ¶¶ 113–20, 202–09, 213–15, 220, 223–24, 247, 249–52, 284.) Ultimately, the ship hold resulted in BD downgrading its revenue guidance amount by \$400 million for FY20, which was attributed “entirely [to] the Alaris pump issue.” (TAC ¶¶ 241–48, 287.)

While the facts regarding the importance of Alaris to BD are largely unchanged from Plaintiff's allegations found within the Second Amended Complaint, Plaintiff has now alleged the "other individualized allegations that further suggest that [Polen] had knowledge of the fact in question." *In re Heartland Payment Sys.*, 2009 WL 4798148, at *7. These allegations, collectively, demonstrate the relative importance of Alaris to BD, and thus the core operations doctrine serves as another piece of the "puzzle" weighing in favor of finding that Polen acted with scienter. *PTC*, 2017 WL 3705801, at *17 ("It seems implausible that [the CEO and CFO] were not paying close attention to the results" of an important drug trial which failed to meet the FDA's standards for approval); *see also In re Allergan Generic Drug Pricing Sec. Litig.*, 2019 WL 3562134, at *12 (D.N.J. Aug. 6, 2019) (scienter well-pleaded where misrepresentations concerned three drugs constituting "substantial portion" of revenues and operations); *Enzymotec*, 2015 WL 8784065, at *18 (scienter inferred where "matter at issue [wa]s central to the core business of the Company,[] about which Defendants spoke regularly").

Polen's Stock Trades. Stock sales can support an inference of scienter when they are "unusual in scope or timing." *In re Synchronoss Techs., Inc. Sec. Litig.*, 2019 WL 2849933, at *15 (D.N.J. July 2, 2019); *In re Par Pharm. Sec. Litig.*, 2009 WL 3234273, at *10 (D.N.J. Sept. 30, 2009) (stock sales "in combination with [p]laintiffs' other allegations . . . reinforce the Court's conclusion that the [complaint] states a claim"). However, the mere fact of trading during an alleged class period is not enough. *In re Burlington Coat Factory*, 114 F.3d at 1424. Whether a sale is "unusual in scope" depends on factors such as "the amount of profit made, the amount of stock traded, the portion of stockholdings sold, or the number of insiders involved." *Wilson v. Bernstock*, 195 F.Supp.2d 619, 635 (D.N.J. 2002) (citation omitted). Other factors relevant to the scope and timing of the sales are whether the sales were "normal and routine," and whether the

profits were substantial relative to the seller's ordinary compensation. *In re Burlington Coat Factory*, 114 F.3d at 1423.

As the Court explained in the September 2021 Decision, the relative magnitude Polen's retained holdings—he sold approximately 18% of his total common stock holdings during the Class Period—weigh against finding that he had motive to commit fraud. *Compare In re Party City Sec. Litig.*, 147 F. Supp. 2d 282, 313–14 (D.N.J. 2001) (“Low aggregate sales and large retained aggregate holdings rebut an inference of motive, even where some defendants have sold significant percentages.”) *with In re Suprema*, 438 F.3d 256, 277 (3d Cir. 2006) (denying motion to dismiss where defendants sold 51% and 38% of their holdings, respectively). Similarly, the allegations regarding the timing of the trades do not lead the Court to conclude that the timing weighs heavily in favor of finding scienter: His sales “exceeded those he made in the three-month (93-day) period directly preceding the Class Period” by some unalleged amount and exceeded those made during the same three-month period the year before (November 5, 2018 to February 5, 2019) by 18%. Finally, Plaintiff emphasizes the dollar value of the stock that Polen sold during the Class Period—\$3,749,744.41—and argues that the large dollar amount establishes a strong inference of scienter no matter the proportion of their holdings that was sold. While sizeable stock sales can weigh in favor of finding an individual acted with scienter, the Court does not see Polen's sales as so substantial as to significantly weigh in favor of finding scienter here. *Cf. Urb. Outfitters*, 103 F. Supp. 3d 635, 654 (E.D. Pa. 2015) (scienter found where defendant retained 94% of holdings but sold 1.2 million shares for profits of \$50 million).

Ultimately, whether an individual's trading history supports or rebuts an inference of scienter is a contextual inquiry that considers the totality of the circumstances of the trades. *In re Toronto-Dominion Bank Sec. Litig.*, 2018 WL 6381882, at *5 (D.N.J. Dec. 6, 2018). While the

totality of the circumstances concerning Polen's trading history does not meaningfully weigh in favor of finding scienter, they are unnecessary to the finding that Plaintiff has met its burden here.³⁰

ii. *Plaintiff has not met its burden with respect to Forlenza, Reidy, or Gallagher*

In contrast to Plaintiff's allegations regarding Polen, the TAC fails to set forth any individualized allegations that would support the strong inference that these three individuals acted with scienter at the time they made their respective statements. While Plaintiff contends that the TAC includes "specific allegations that the Defendants were personally informed about the content of the meetings with the FDA and the basis for the resulting ship hold" (Pltf.'s Br. at 44), the allegations on which they rely are fatally vague.

The TAC alleges that, when the decision to implement a ship hold was made following the Fall 2019 Meeting, "all senior leaders of the business units, and the corporate leaders" were made aware of "what had happened," "the decision was given to Shkolnik, the Chief Quality Officer [Boisier,] and up to the CEO," and "[e]veryone was involved." (TAC ¶ 145.) While Plaintiff points to the allegations demonstrating that a number of other confidential witnesses were aware of the meeting or other information concerning the ship hold (*e.g.*, TAC ¶¶ 138–144), they do not make any individualized showing as to Forlenza, Reidy, or Gallagher. Similarly vague are the TAC's allegations which purport to demonstrate that Forlenza and Reidy were aware that the meeting with the FDA in January 2020 resulted in the reinstatement of the ship hold: The TAC merely alleges that the resumption of the ship hold in January 2020 was "reported up the chain of command" and news "quickly went to everyone." (TAC ¶ 190.) These "blanket assertions" that Forlenza, Reidy, and Galagher "'knew' that the representations were untrue" are plainly

³⁰ Because Plaintiff has met its burden of establishing scienter as to Polen, it has done the same with respect to BD. *E.g.*, *Horizon Lines*, 713 F. Supp. 2d at 402.

insufficient. *Klein*, 147 F. App'x at 277; *see, e.g., Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 591 (S.D.N.Y. 2011) (confidential witness's "allegations must show that individual defendants actually possessed the knowledge highlighting the falsity of public statements").³¹

In the absence of any allegations demonstrating that these individuals had personal knowledge supporting a strong inference of scienter, Plaintiff's reliance on other articulated factors—including the detailed nature of the individuals' public statements or the core operations doctrine—is unavailing. *See, e.g., In re Heartland Payment Sys., Inc. Sec. Litig.*, 2009 WL 4798148, at *7 (D.N.J. Dec. 7, 2009) ("[T]here must be other, individualized allegations that further suggest that the officer had knowledge of the fact in question."). Nor does Forlenza's trading history materially alter the analysis, as the value of the stock sold, the amount of Forlenza's retained holdings, the timing of the sales, the number of insiders involved are not so unusual in scope as to give rise to a strong inference of scienter. *See* ECF No. 87 at 37–40.

3. Plaintiff sufficiently pleads loss causation.

A plaintiff pleads loss causation by providing a "short and plain statement" giving defendants "some indication of the loss and the causal connection that [it] has in mind." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 346–47 (2005). A plaintiff must plead that "the truth became known" when a corrective disclosure occurred, causing a stock price drop from which the plaintiff claims a loss. *Id.*, 544 U.S. at 347. The Third Circuit instructs that courts should take a "practical approach" to loss causation, applying "general causation principles" under which a plaintiff must show that "the misrepresentation touches upon the reasons for the investment's

³¹ This conclusion does not stem from any indication that FE-6's allegations are unreliable. Rather, with respect to the scienter-related allegations concerning Forlenza, Reidy, and Gallagher, the TAC lacks meaningful detail by which the Court could find that Plaintiff has met its burden. By contrast, Plaintiff's allegations regarding Polen are sufficient to establish *how* Polen was aware of the meeting when the TAC alleges with specificity the reporting chain which led from FE-6 to Polen. *Supra* at 32.

decline.” *McCabe*, 494 F.3d at 426, 428. This “highly factual” inquiry is “often unsuited to disposition . . . on the pleadings.” *Merck*, 2011 WL 3444199, at *29.

While Defendants contend that the Company’s February 6, 2020 announcement disclosing the nature of BD’s communications with the FDA did not reveal any “hidden ‘truth’” (Dfts.’ Br. at 53–54), the TAC sufficiently alleges that the BD made actionable, misleading statements to the investing public. *See supra* Section II.A. The TAC adequately pleads the link between these misrepresentations and Plaintiff’s loss following the February 6, 2020 disclosure of the FDA’s views regarding Alaris and the need for new 510(k) clearance. *Merck*, 2011 WL 3444199, at *29, *32 (loss causation alleged where public release of information revealing misleading nature of prior statements was substantial cause of stock price drop). This link is further supported by contemporaneous comments by various investment analysts regarding the previously unknown information about the severity of Alaris’s regulatory issues and software issues previously minimized as “upgrade[s].” (TAC ¶ 251.)

B. Section 20(a) Claim

Section 20(a) of the Exchange Act “creates a cause of action against individuals who exercise control over a ‘controlled person,’ including a corporation, that has committed a violation of § 10(b).” *Avaya*, 564 F.3d at 252; *see also* 15 U.S.C. § 78t(a). A Section 20(a) claim thus imposes secondary liability on the controlling person for the wrong committed by the one who is controlled. *In re Suprema*, 438 F.3d at 284–85. Because Plaintiff has sufficiently alleged an actionable Section 10(b) and Rule 10b-5 violation, Plaintiff has stated a claim against Polen. *Bing Li v. Aeterna Zentaris, Inc.*, 2016 WL 827256, at *4 (D.N.J. Mar. 2, 2016). Plaintiff has not done so with respect to Forlenza or Reidy.

C. Section 20A Claim

Section 20A(a) of the Exchange Act provides that “[a]ny person who violates any provision of . . . [the Exchange Act] or the rules or regulations thereunder by purchasing or selling a security while in possession of material, nonpublic information shall be liable . . . to any person who, contemporaneously with the purchase or sale of securities that is the subject of such violation, has purchased . . . securities of the same class.” To establish a violation under Section 20A of the Exchange Act, Plaintiff must, among other things, first identify a predication violation of the Exchange Act. *See City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 167 (3d Cir. 2014). Plaintiff has done so with respect to Polen, and further alleged Polen was in possession of material, nonpublic information when he sold 13,907 shares of BD common stock in open market sales, exclusive of sales to the issuer. (TAC ¶ 359.) Contemporaneous with his sales, Plaintiff purchased 23,754 shares of BD common stock at inflated prices. (TAC ¶ 360.) Plaintiff has thus sufficiently pleaded its claim against Polen, but not Forlenza, pursuant to Section 20A. *In re Valeant Pharms. Int’l, Inc., Sec. Litig.*, 2019 WL 2724075, at *5 (D.N.J. June 30, 2019).

III. CONCLUSION

For the reasons discussed in this Opinion, the Court will grant in part and deny in part Defendants’ motion. All counts against Defendants Forlenza and Reidy shall be dismissed. Furthermore, Plaintiff’s claims concerning the statements found within the February 4 Recall Notices are dismissed for failure to plausibly allege a material misstatement or omission. An appropriate Order will issue.

/s/ Stanley R. Chesler
 STANLEY R. CHESLER
 United States District Judge

Dated: August 11, 2022